

MAY 23 2003

K031262 (P. 1 of 2)

## 510(K) SUMMARY

### 1. SUBMITTER:

NDO Surgical, Inc.  
125 High St.  
Mansfield, MA 02048  
Telephone: 508-337-8881  
Fax: 508-337-8882

Contact: Eric Bannon, Vice President, Regulatory, Clinical, QA  
Date Prepared: March 24, 2003

### 2. DEVICE:

Trade Name: NDO Surgical Endoscopic Plication System  
Class: II  
Classification Name: Endoscope and accessories

### 3. PREDICATE DEVICE:

NDO Surgical Endoscopic Plication System (K023234)

### 4. DEVICE DESCRIPTION:

The NDO Surgical Endoscopic Plication System is a device intended to deliver an implant in the stomach near the Gastroesophageal Junction that creates a full thickness plication for the treatment of Gastroesophageal Reflux Disease (GERD). The EPS consists of three components: the Endoscopic Plication Instrument, the Retractor and the Implant Cartridge. The Implant Cartridge and retractor are loaded onto the instrument; this is then passed transorally into the stomach to create the plication. The instrument's shaft, which comes into contact with the patient, is made of polyvinyl chloride. The retractor is made of surgical grade stainless steel, with a polycarbonate sheath. The implant is comprised of two titanium tees, 2.0 polypropylene suture and two ePTFE pledgets. The implant is housed in a disposable cartridge. Once the system has been introduced into the stomach, the retractor is engaged into the gastric mucosa and the tissue is retracted into the arms of the instrument. The arms of the instrument are closed and the implant is deployed, creating the full thickness, serosa-to-serosa plication.

## **5. INTENDED USE:**

The NDO EPS System is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

## **6. COMPARISON OF CHARACTERISTICS:**

The proposed Endoscopic Plication System, is an updated design of the predicate device, it is therefore similar in intended use and function. The design changes made were a result of feedback from users in regard to ergonomic changes. Additionally, changes were made to system to make the instrument more manufacturable.

The proposed and predicate devices utilize the same method of creating and placing a plication, however the revised design employs a modified titanium component to achieve the same result. Lastly, the indications being requested for the proposed EPS are already cleared for the predicate EPS.

## **7. PERFORMANCE DATA:**

Bench top, In-Vivo simulated use and ex-vivo performance testing was provided in support of the substantial equivalence determination.

The testing demonstrates substantially equivalent performance between the two devices



MAY 23 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Eric Bannon  
Vice President, Regulatory, Clinical  
and Quality Assurance  
NDO Surgical, Inc.  
125 High Street  
Mansfield, Massachusetts 02048

Re: K031262  
Trade/Device Name: Endoscopic Plication System  
Regulation Number: 21 CFR 876.1500  
Regulation Name: Endoscope and accessories  
Regulatory Class: II  
Product Code: KOG  
Dated: March 27, 2003  
Received: April 25, 2003

Dear Mr. Bannon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

*Miriam C. Provost*  
for Celia M. Witten, Ph.D., M.D.

Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

ATTACHMENT 1

510(k) Number (if known): K031262

Device Name: Endoscopic Plication System

Indications for Use: The NDO EPS System is indicated for the treatment of the symptoms of chronic gastroesophageal reflux disease (GERD) in patients who require and respond to pharmacological therapy.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒  
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

Miriam C. Provost  
(Division Sign-Off)  
Division of General, Restorative  
and Neurological Devices

(Optional Format 1-2-96)

510(k) Number K031262